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TITLE: Modifiers of the Efficacy of Risk-Reducing Salpingo-Oophorectomy for the Prevention of Breast and Ovarian Cancer in Carriers of BRCA1 and BRCA2 Mutations

PRINCIPAL INVESTIGATOR: Noah D. Kauff, M.D.

CONTRACTING ORGANIZATION: Sloan-Kettering Institute for Cancer Research
New York, NY 10021

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The principle investigator was funded via a Physician-Scientist Training Award to participate in a comprehensive training plan to foster the transition to independent clinical breast cancer researcher. This plan included 1) conduct of a prospective study examining modifiers of the efficacy of risk-reducing salpingo-oophorectomy for the prevention of breast and ovarian cancer in carriers of BRCA mutations; and 2) participation in a structured training program in research methodology, biostatistics, molecular biology, and ethics. Progress from 5/1/2006 – 4/30/2007 includes: 1) Submission for publication the first prospective data examining the efficacy of risk-reducing salpingo-oophorectomy for the prevention of BRCA-associated breast and gynecologic cancer when BRCA2 mutation carriers are examined separately from BRCA1 mutation carriers.; 2) Continuation of training in genetic epidemiology, laboratory methods, outcomes analysis, and conduct of clinical research, through participation in the weekly laboratory meetings of Kenneth Offit, MD, MPH, in addition to formal mentoring ; and 3) Continued progress on a genetic epidemiologic, computational and structural analysis of BRCA2 variants of uncertain significance funded by a peer-reviewed NIH award (1 R03 CA119265-01 to N.D.K.) to the principal investigator of this PTSA.

15. SUBJECT TERMS
BRCA1, BRCA2, Breast Cancer, Ovarian Cancer, Prophylactic Surgery

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Table of Contents

Introduction

The principle investigator was funded beginning on May 1, 2003 by the Department of Defense Breast Cancer Research Program via a Physician-Scientist Training Award (PTSA) to participate in a comprehensive training plan designed to assist the principal investigator in making the transition from junior faculty member to independent clinical breast cancer researcher. There were two chief components of the plan. The first component was the conduct of a prospective research study entitled, "Modifiers of the Efficacy of Risk-Reducing Salpingo-Oophorectomy for the Prevention of Breast and Ovarian Cancer in Carriers of *BRCA1* and *BRCA2* Mutations," under the direction and mentorship of Kenneth Offit, M.D., M.P.H. The second component of the comprehensive training plan was for the principal investigator to participate in didactic coursework and structured training in research methodology, biostatistics, methods of molecular biology, and ethics of clinical research. This progress report will summarize progress and accomplishments made as well as difficulties and challenges encountered during the fourth year of this award that ran from May 1, 2006 through April 30, 2007.

1) Progress on Research Project Component of Award

The principal investigator in concert with a multidisciplinary team at Memorial Sloan-Kettering Cancer Center (MSKCC) reported the first prospective evaluation of the role of salpingo-oophorectomy in reducing the risk of both breast cancers and *BRCA*-related gynecologic (ovarian, fallopian tube, and primary peritoneal) cancers in carriers of *BRCA1* and *BRCA2* mutations. In that study, we demonstrated that risk-reducing salpingo-oophorectomy (RRSO) is associated with a decreased combined incidence of breast and *BRCA*-related gynecologic cancer. While these results were encouraging, there were important limitations in that preliminary data that needed to be addressed to allow better tailoring of risk reduction strategies for women at inherited risk secondary to a mutation in either *BRCA1* or *BRCA2*.

In order to address some of these issues, with the assistance of the PSTA, we have been conducting a prospective study to address the following three specific aims: #1) determine the degree of protection conferred by RRSO for the prevention of subsequent breast and *BRCA*-related gynecologic cancer in a) carriers of *BRCA1* mutations and b) carriers of *BRCA2* mutations; #2) determine the effect of RRSO on cancer-specific mortality in carriers of *BRCA1* and *BRCA2* mutations; and #3) determine the effect in carriers of *BRCA* mutations of RRSO on the incidence of a) subsequent breast cancer and b) subsequent *BRCA*-related gynecologic cancer.

The study plan was to ascertain women with a *BRCA1* or a *BRCA2* mutation, who have undergone genetic counseling at MSKCC, and who had not undergone bilateral oophorectomy prior to the time of receipt of genetic test results. Uptake of RRSO or use of ovarian surveillance is determined for study participants by a combination of annual questionnaire, telephone contact, and medical record review. The time to cancer or time to cancer-specific mortality is analyzed for each of the specific aims using Kaplan-Meier analysis and a Cox proportion hazards model. Total planned accrual through April 30, 2007 was 452 participants with ovarian tissue at risk and 348 participants with both breast and ovarian tissue at risk. Actual accrual through April 30, 2007 was 507 participants with ovarian tissue at risk and 431 with both breast and ovarian tissue at risk exceeding planned accrual by 12% and 24% respectively.

While we exceeded our target accrual, in order to further increase the power of study, we also initiated a collaboration with Dr. Timothy Rebbeck of the University of Pennsylvania and the Prevention and Observation of Surgical Endpoints (PROSE) study group. In this collaboration, we have combining our updated prospective follow-up data with data obtained from a similar prospective follow-up study being conducted at 10 North American and European centers. This collaboration has resulted in the ascertainment of a total 886 *BRCA* mutation carriers (597 with breast tissue at risk) in which a mean of 40 months of prospective follow-up is available. We have completed preliminary analysis on this combined

cohort of the planned endpoints for specific aims #1 and #3 and presented this data as an oral presentation at the 2006 Meeting of the American Society of Clinical Oncology. Additionally, a manuscript from this collaboration has been submitted for publication (findings summarized below) and is currently undergoing peer review.

Specific components of the statement of work for June 2006 – May 2007 relevant to the research component of the training award:

a) June 2006 - Sept 2006: Preparation of manuscripts based on data collected through the 3rd interim analysis.

   This component of the statement of work was conducted from June 2006 through April 2007 and resulted in the submission of a manuscript addressing the planned endpoints of specific aims #1 and #3 to the New England Journal of Medicine in November 2006. Although the manuscript was not ultimately accepted for publication, comments from the four reviewers were used to revise the manuscript which was re-submitted for publication on April 27, 2007 and, as noted above, currently undergoing peer review.

b) April 2007 - May 2007 – 4th Interim Data Analysis

   This data analysis was completed as scheduled as part of the manuscript revision process described above.

c) Additional work relevant to the research component of the award not specifically outlined in the original statement of work.

   The principal investigator has made continued progress on work supported by an R03 award from the NCI Cancer Prevention Research Small Grant Program (1 R03 CA119265-01 to N.D.K.) to conduct a combined structural, computational and epidemiologic analysis of *BRCA2* missense mutations of uncertain clinical significance. Further details of this project were previously described in the June 2006 Progress Report.

   In May 2007, the principal investigator was nominated for a Fiscal Year 2007 Department of Defense Breast Cancer Research Era of Hope Scholar Award. Decisions regarding invitations to submit a full proposal are expected June 22, 2007.

2) Progress of Didactic Training Component of Award

Part of the time freed by the PSTA was also to be used by the Principal Investigator to participate in formal coursework and training in research methodology, biostatistics, methods of molecular biology, and ethics of clinical research. Specifics accomplishments relevant to this award are detailed below.

Specific components of the statement of work for June 2006 – May 2007 relevant to the didactic and practical training component of the training award:

a) June 2006 - May 2007: Participation in Weekly Meeting of the Diagnostic Molecular Genetics Laboratory at MSKCC.

   The principal investigator continued to be an active participant in these meetings, and with the continued mentorship of Kenneth Offit, MD, MPH, directed the ongoing genetic epidemiologic,

computational and structural analysis of *BRCA2* variants of uncertain significance (supported by 1 R03 CA119265-01 to N.D.K.)

3) Specific Research Findings Supported by This Award

A) Submitted data for publication from our multi-center collaboration to prospectively evaluate efficacy of risk-reducing salpingo-oophorectomy (RRSO) for the prevention of *BRCA*-associated breast and gynecologic cancer when carriers are stratified by mutation status.

In last year's progress report, we reported preliminary findings from a collaboration with investigators from the University of Pennsylvania (Rebbeck TR, Domchek S) and the PROSE study group addressing impact of RRSO on subsequent breast cancer risk when *BRCA2* mutation carriers were evaluated separately from *BRCA1* mutation carriers. In the intervening year, we have further refined this analysis and submitted the results (summarized below) for publication.

Briefly, we prospectively evaluated 1079 women ≥ 30 years of age, with ovaries in-situ and a deleterious mutation in *BRCA1* or *BRCA2* identified at one of eleven academic referral centers from 11/1/1994 to 12/1/2004. Follow-up information through 11/30/2005 was collected by questionnaire and medical record review. We then analyzed the effect RRSO had on time to diagnosis of breast or *BRCA*-associated gynecologic cancer using a Cox proportional-hazards model. During 3 years follow-up, RRSO was associated with an 85% reduction in *BRCA1*-associated gynecologic cancer risk (HR=0.15, 95% CI: 0.04 – 0.56) and a 72% reduction in *BRCA2*-associated breast cancer risk (HR=0.28, 95% CI: 0.08 – 0.92). While protection against *BRCA1*-associated breast cancer (HR=0.61, 95% CI: 0.30 – 1.22) and *BRCA2*-associated gynecologic cancer (HR=0.00, 95% CI: not estimable) was suggested, neither effect reached statistical significance. These results suggest that the protection conferred by RRSO against breast and gynecologic cancers may differ between carriers of *BRCA1* and *BRCA2* mutations and that further studies evaluating the efficacy of risk reduction strategies in carriers of *BRCA1* and *BRCA2* mutations should stratify by the specific gene mutated.

Additionally, in an exploratory analysis, it appeared as though RRSO was profoundly protective against ER-positive invasive breast cancer (HR = 0.22, 95% CI: 0.05-1.05, p=0.058) but RRSO did not appear to confer protection against ER-negative disease (HR = 1.10, 95% CI: 0.48-2.51, p=0.82). If these results are confirmed, it could have profound implications for breast cancer risk-reduction strategies in women with *BRCA1* or *BRCA2* mutations.

Key Research Accomplishments

- Submitted for publication the first prospective study to evaluate the impact of RRSO for breast and gynecologic cancer prevention in *BRCA2* mutation carriers separately form *BRCA1* mutation carriers.

- Presented data questioning the role of ovarian hormone ablation in the prevention of ER-negative cancer in women with *BRCA1* or *BRCA2* mutations.

Reportable Outcomes

- None

Conclusions

With continued support of the PTSA, the principle investigator is making the transition to becoming an independent clinical breast cancer researcher. As evidence of this, the principal investigator has successfully obtain NIH peer-reviewed funding and has published over 31 peer-reviewed publications (including ten first author reports) in Journals such as the *Journal of the National Cancer Institute*, the *Journal of Clinical Oncology*, *Cancer*, *JAMA* and the *New England Journal of Medicine*. (See attached biosketch.) Additionally, the principal investigator is becoming a national and international leader as evidence by his appointments to the Editorial Board of the *Journal of Clinical Oncology,* the Cancer Prevention and Control Committee of the Gynecologic Oncology Group and the Education Committee of the Society of Gynecologic Oncologists. It is anticipated that ongoing support from the PTSA will continue to advance the principal investigator's development into a highly productive, independent clinical breast cancer researcher.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Photocopy this page or follow this format for each person.

NAME Noah D. Kauff, M.D.	POSITION TITLE Assistant Attending Physician Clinical Genetics Service, Dept. of Medicine Gynecology Service, Dept. of Surgery

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Amherst College, Amherst, MA	B.A. cum laude	1986	Chemistry and Political Science
University of Pennsylvania School of Medicine Philadelphia, PA	M.D.	1993	Medicine

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application.

PROFESSIONAL EXPERIENCE

1993-1995 Intern/Resident in Obstetrics and Gynecology
Tufts University New England Medical Center, Boston, MA

1995-1997 Resident in Obstetrics and Gynecology,
New York Medical College, New York, NY

1997-1998 Co-Executive Chief Resident in Obstetrics and Gynecology
New York Medical College, New York, NY

1998-2000 Attending Obstetrician/Gynecologist,
Director – Hereditary Breast and Ovarian Cancer Screening Program
Women's Health Care Associates, Newton, NJ

2000-2002 Fellow in Clinical Genetics
Memorial Sloan-Kettering Cancer Center/New York Presbyterian Hospital, New York, NY

2002-Present Clinical Assistant (2002-2004) / Assistant Member (2004-Present)
Memorial Sloan-Kettering Cancer Center, New York, NY

2002-Present Clinical Assistant Physician (2002-2005) / Assistant Attending Physician (2005-Present)
Clinical Genetics Service, Department of Medicine
Gynecology Service, Department of Surgery
Memorial Hospital for Cancer and Allied Diseases, New York, NY

2006-Present Director, Ovarian Cancer Screening and Prevention Program
Gynecology Service, Department of Surgery
Memorial Hospital for Cancer and Allied Diseases, New York, NY

HONORS

1989-93 John Woodruff Simpson Fellow in Medicine, Univ. of Pennsylvania School of Medicine, Phila., PA
Mar 1997 Felix Rutledge Fellow in Gynecologic Oncology, MD Anderson Cancer Center, Houston TX
May 1998 New York Medical College, Department of Ob/Gyn, Resident Research Award, Valhalla, NY
May 2001 American Society of Clinical Oncology Merit Award, San Francisco, CA
May 2002 American Society of Clinical Oncology Merit Award, Orlando, FL
June 2002 Nergesh Tejani Award for Research/Academic Excellence, New York Medical College, Valhalla, NY

OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS

Dec 2001-Present Fellow, American College of Obstetricians and Gynecologists
August 2005-Present Society of Gynecologic Oncologists, Hereditary Cancer Educational Resource Panel
Dec 2005-Present Gynecologic Oncology Group, Cancer Prevention and Control Committee
Jan 2007-Present Editorial Board, Journal of Clinical Oncology

SELECTED PUBLICATIONS (in chronological order)

(Publications selected from 33 peer-reviewed publications)

1. **Kauff ND**, Scheuer L, Robson ME, Glogowski E, Kelly B, Barakat R, Heerdt A, Borgen PI, Davis JG, Offit K. Insurance Reimbursement for Risk-Reducing Mastectomy and Oophorectomy in Women with *BRCA1* or *BRCA2* Mutations. Genetics in Medicine 2001; 6:422-5.
2. Scheuer L, **Kauff N**, Robson M, Kelly B, Barakat R, Satagopan J, Ellis N, Hensley M, Boyd J, Borgen P, Norton L, Offit K. Outcome of Preventive Surgery and Screening for Breast and Ovarian Cancer in *BRCA* Mutation Carriers. Journal of Clinical Oncology 2002; 20:1260-8.
3. **Kauff ND**, Satagopan JM, Scheuer L, Robson ME, Castiel M, Nafa K, Hensley M, Hudis CA, Ellis NA, Boyd J, Borgen PI, Barakat RR, Norton L, Offit K. Risk-Reducing Salpingo-Oophorectomy in Women with *BRCA1* and *BRCA2* Mutations. New England Journal of Medicine 2002; 346:1609-15.
4. **Kauff ND**, Perez-Segura P, Robson ME, Scheuer L, Siegel B, Schluger A, Rapaport B, Frank TS, Nafa K, Parmigiani G, Offit K. Incidence of Non-Founder *BRCA1* and *BRCA2* Mutations in High-Risk Ashkenazi Breast and Ovarian Cancer Families. Journal of Medical Genetics 2002; 39:611-614.
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6. **Kauff ND**, Brogi E, Scheuer L, Pathak DR, Borgen PI, Hudis CA, Offit K, Robson ME. Epithelial Lesions in Prophylactic Mastectomy Specimens from Women with *BRCA* Mutations. Cancer 2003; 97:1601-8.
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8. **Kauff ND,** Barakat RR. Surgical Risk-Reduction in Carriers of *BRCA* Mutations: Where Do We Go from Here? Gynecologic Oncology 2004; 93:277-9.
9. Kirchhoff T, **Kauff ND**, Mitra N, Nafa K, Huang H, Palmer C, Gulati T, Donat S, Robson ME, Ellis NA, Offit K. *BRCA* Mutations and Risk of Prostate Cancer in Ashkenazi Jews. Clinical Cancer Research 2004; 10:2918-21.
10. Dupont J, Tanwar MK, Thaler HT, Fleisher M, **Kauff N,** Hensley ML, Sabbatini P, Anderson S, Aghajanian C, Holland EC, Spriggs DR. Early Detection and Prognosis of Ovarian Cancer Using Serum YKL-40. Journal of Clinical Oncology 2004; 22:3330-9.
11. Siddiqui R, Onel K, Facio F, Nafa K, Diaz LR, **Kauff N**, Huang H, Robson M, Ellis N, Offit K. The TP53 mutational spectrum and frequency of CHEK2*1100delC in Li-Fraumeni-like kindreds. Familial Cancer 2005; 4:177-81.
12. **Kauff ND**, Hurley KE, Hensley ML, Robson ME, Lev G, Goldfrank D, Castiel M, Brown CL, Ostroff JS, Hann LE, Offit K, Barakat RR. Ovarian Cancer Screening in Women at Intermediate Risk - Impact on Quality of Life and Need for Invasive Follow-up. Cancer 2005; 104: 314-20.
13. (**Kauff ND** - Principal Author) Society of Gynecologic Oncologists: Clinical Practice Committee. Statement on Prophylactic Salpingo-oophorectomy. Gynecologic Oncology. 2005; 98:179-181.
14. **Kauff ND**, Mitra M, Robson ME, Hurley KE, Chuai S, Goldfrank D, Wadsworth E, Lee J, Cigler T, Borgen PI, Norton L, Barakat RR, Offit K. Risk of Ovarian Cancer in BRCA1 and BRCA2 Mutation Negative Hereditary Breast Cancer Families. Journal of the National Cancer Institute. 2005; 97:1382-4.
15. Offit K, **Kauff ND**. Reducing the risk of gynecologic cancer in the Lynch syndrome. New England Journal of Medicine. 2006; 354:293-5.
16. Goldfrank D, Chuai S, Bernstein JL, Ramon y Cajal T, Lee JB, Alonso MC, Diez O, Baiget M, **Kauff ND**, Offit K, Robson M. Impact of Mammography on Breast Cancer Risk in Women with Mutations in *BRCA1* or *BRCA2*. Cancer Epidemiology, Biomarkers and Prevention 2006; 15:2311-3.
17. Lu KH, **Kauff ND**. Does a *BRCA* Mutation Plus Tamoxifen Equal Hysterectomy? Gynecologic Oncology 2007; 104:3-4.
18. Modica I, Soslow R, Black D, Tornos C, **Kauff N**, Shia J. Utility of Immunohistochemistry in Predicting Microsatellite Instability in Endometrial Carcinoma. American Journal of Surgical Pathology 2007; 31:744-51.
19. **Kauff ND**, Barakat RR. Risk-Reducing Salpingo-Oophorectomy in Patients with Germline Mutations in *BRCA1* or *BRCA2*. Journal of Clinical Oncology (In Press)
20. **Kauff ND**, Offit K. Modeling Genetic Risk for Breast Cancer. JAMA (In Press)
21. Smith KL, Adank M, **Kauff N**, Lafaro K, Boyd J, Lee JB, Hudis C, Offit K, Robson M. *BRCA* Mutations in Women with Ductal Carcinoma *in situ*: Prevalence and Risk Factors. Clinical Cancer Research (In Press)

CURRENT RESEARCH SUPPORT:

Ongoing Research Support

DAMD17-03-1-0375 Kauff (PI) 5/1/2003 – 4/30/2008
Department of Defense Breast Cancer Research Program

Modifiers of the Efficacy of Risk-Reducing Salpingo-Oophorectomy for the Prevention of Breast and Ovarian Cancer in Carriers of *BRCA1* and *BRCA2* Mutations

The major goal of this project is to prospectively analyze the impact of genetic and environmental modifiers to the protection conferred by risk-reducing salpingo-oophorectomy for the prevention of breast and *BRCA*-related gynecologic cancer in carriers of *BRCA1* and *BRCA2* mutations.

Role: Principal Investigator

1 R03 CA119265-01 Kauff (PI) 9/28/2005 – 8/31/2007
NIH/National Cancer Institute

Structural, Computational and Epidemiologic Analyses of *BRCA2* Missense Mutations

The major goal of this project is to conduct a combined structural, computational and epidemiologic analysis of frequently reported *BRCA2* missense mutations to elucidate their clinical significance.

Role: Principal Investigator

1 R01 CA79572 Winawer (PI) 4/1/2003 – 3/31/2008
NIH/National Cancer Institute

Screening Colonoscopy Feasibility Trial

The goal of this multi-institutional, randomized trial of 3550 participants is to compare benefits and harms of a single screening colonoscopy with annual FOBT directed colonoscopy.

Role: Chair of Genetics Review Committee